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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/125,114	08/18/1998	IAN ASHLEY PRICE	P8129-8004	7439
6449	7590	10/03/2006	EXAMINER	
ROTHWELL, FIGG, ERNST & MANBECK, P.C. 1425 K STREET, N.W. SUITE 800 WASHINGTON, DC 20005			WANG, SHENGJUN	
			ART UNIT	PAPER NUMBER
			1617	

DATE MAILED: 10/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/125,114

Applicant(s)

PRICE, IAN ASHLEY

Examiner

Shengjun Wang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39-47 and 52-74 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39-47 and 52-74 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 26, 2006 has been entered.

Claim Rejections 35 U.S.C. 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 39-47, 52-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Armitage et al US Patent 5,696,165.

4. The scope of the instant claims are directed to solid compressed composition comprising racemic ibuprofen in the form of sodium salt in amount of at least 35% by weight of the composition, a compressible filler combined with a disintegrant, and sodium carbonate in amount of about 3-20%. The claimed composition also contains various functional limitations, which are either attributed to its intended use or its process of making. For example the recitation of "non-effervescent" dosage form is viewed as an intended use limitation because once the

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individual components of the instant claims are described in a prior art composition, the prior art composition is expected to provide the claimed intended use.

5. The limitations directed to compression force and crushing strength are also directed to the process of making the dosage form. Examiner states composition claims that are drafted as "product by process" are not limited to the manipulations of the recited steps, only the structure implied by the steps. (see MPEP 2113). "Even though product - by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product - by - process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985).

6. Thus, Applicant is placed on notice that the recited functional limitations do not appear to affirmatively limit the scope of the claimed composition.

7. Armitage teaches solid compositions comprising sodium salt of S(+) ibuprofen and sodium carbonate in the form of granules (see col. 16, example 18). The formulation of Armitage contains 16.5% ibuprofen salt and 4.6 % of sodium carbonate. The granule formulations of Armitage can have up to about 99% ibuprofen, therefore, Armitage teaches the concentrations of the instant claims. (see col. 22, lines 24-37). Armitage further teaches the use of fillers and disintegrants in his formulations including lactose, croscarmellose, cyclodextrin, etc...(see col. 22, lines 20-40; col. 2, line 66-col 3, line 43). Armitage further teaches film coating of his oral compositions (see col. 15-17). The particular Armitage's granules are described as effervescent granules because they contain malic acid/sodium bicarbonate effervescent couple.

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However, since Armitage's composition contains all components of the instant claims, it can also be used as a non-effervescent formulation with or without the malic acid/bicarbonate. It is noted that solid non-effervescent composition are preferred by Armitage et al. See, col. 4, lines 23-26. It would have been obvious to add sodium carbonate in a solid non-effervescent composition since sodium carbonate is disclosed as a suitable excipient in ibuprofen composition.

8. Armitage only fails to describe the compression characteristics of the instant compositions.

9. However, it would have been obvious to one of ordinary skill in the art at the time of invention to optimize the compression force and crushing strength by routine experimentation to formulate a commercially and therapeutically feasible composition. Newly added claim 74, drawn to a method of enhancing the compressibility of the ibuprofen composition by adding sodium carbonate to the composition, is properly rejected for reasons set forth above as it has been shown that adding sodium carbonate would have been obvious. As to the limitation "enhancing the compressibility," it is noted that the limitation has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

It is noted that Armitage teach the use of single enantiomer, and do not teach expressly a racemic mixture. However, this would not help applicants' non-obvious arguments. As disclosed

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by Armitage, the (+)-ibuprofen is the active agents, and is better than the racemic mixture.

Racemic mixture of ibuprofen is well known in the art. (col. 1, lines 5-24. It is well settled that Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." In re Gurley, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994). Further, optical enantiomers or their mixture are expected to be similar in their physical and chemical properties. See In re Anthony 162 USPQ 594; In re Adamson 125 USPQ 233. Further omitting an ingredient in a product so that the product would not have the properties due to that ingredient would not produce a distinct and patentable subject matter.

10. Claims 39-47, 52-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Armitage et al US Patent 5,696,165 in view of Arvanitidou et al WO 96/19982.

11. The teachings of Armitage are described above. Armitage does not explicitly that his granules can be used in as a non-effervescent formulation with the presence of sodium carbonate.

12. Arvanitidou is merely used to show that preparing a non-effervescent ibuprofen composition is well recognized in the art and readily employed to prepared ibuprofen containing compositions with the presence of sodium carbonate (see pages 5-6; page 7 last paragraph).

13. Arvanitidou teaches methods of making non-effervescent compositions comprising ibuprofen and an inorganic alkaline salt such as sodium carbonate (see page 5, last paragraph; page 9, examples I-V). Arvanitidou describes that converting the non-effervescent formulation to

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an effervescent formulation merely requires the addition of an organic acid such as citric acid or malic acid (see page 7, 2nd paragraph and page 9, last 3 lines). Arvanitidou only fails to use a racemic ibuprofen salt form.

Nevertheless, it would have been further obvious to one of ordinary skill in the art at the time of invention to merely eliminate the malic acid of Armitage granules to formulate a non-effervescent solid formulation for any patient preferring non-effervescent formulations of ibuprofen. The ordinary skill in the art would have had a reasonable expectation of success, because as shown by Arvanitidou, adding an organic acid to non-effervescent formulations of Ibuprofen to convert a non-effervescent formulation to an effervescent formulation is conventional and well within purview of one of ordinary skill in the art.

Response to the Arguments

Applicants' amendments and remarks submitted have been fully considered, and are found unpersuasive for reasons discussed above.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

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applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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Art Unit 1617